REMARKS

In order to expedite prosecution, Applicants' representative initiated a personal interview with Examiner Menon. Applicants and Applicants' representative would like to thank Examiner Menon for his courtesy in conducting the interview and for his assistance in resolving issues. A summary of the interview discussion follows.

Claims 1, 3, 7, 8 and 10 stand rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed for the following reasons.

The Examiner alleges that "mean maximum fibril length is not clearly defined in the specification or claims as originally filed." As discussed during the interview, it is respectfully submitted that "mean maximum fibril length" and "mean maximum length of pores" are interchangeable phrases describing the same physical arrangement. Indeed, as described on page 13, lines 10-14 of Applicants' specification, the "term 'maximum cross dimension of a pore' as used herein means the maximum cross dimension of the spatial part which constitutes a pore, that is, *the maximum length* that links, across a cross-section, two points on the outer periphery *of a pore* which is formed by a resin part *and fibrils* connected thereto" (emphasis added). That is, the same physical arrangement is described by a "mean maximum fibril length" in relation to the fibrils, and by "mean maximum length of pores" in relation to the pore length.

To better understand this point, the Examiner should consider two concentric circles where the outer circle is juxtaposed with the inner circle. The same interface between the two circles can be described by either the inner diameter of the outer circle or the outer diameter of the inner circle, so that two different structural references can be used to describe the same physical structure (interface). With respect to such relative relationships, fibrils and pore length would be analogous to the inner and outer diameters in the aforementioned example.

During the interview, the Examiner noted that the specification does not provide a nexus between the terminology "fibril length" and "cross dimension of a pore" described on page 13 of the specification. It is respectfully submitted that one of ordinary skill in the art would recognize that the two terms are interchangeable and simply represent a choice-of-words difference, so that the aforementioned "nexus" referenced by the Examiner falls within general knowledge which is inherent to Applicants' specification and need not be expressly described therein. For the Examiner's reference, attached hereto are two technical publications (article entitled "A Small Arterial Substitute" by Campbell et al. and USP No. 6,689,160 to Okuda et al.) which evidence that one of ordinary skill in the art would interpret the terms interchangeably. For example, Campbell et al. references "[f]ibril length (pore size)" (*see* line 7 of Abstract), and Okuda et al. similarly references "pore diameter (fibril length)" (col. 3, line 5). Accordingly, claim 1 has been amended to replace "maximum fibril length" with "maximum length of pores" so as to be consistent with claim 8.

The Examiner further alleges that the recitation "where (X) is a particle diameter of particles captured when the particle trapping ratio is equal to or more than 90 % in the case where the filtration is done under an elevated pressure of 0.1 MPa" should instead recite "where (X) is a smallest particle diameter of particles captured … ." The Examiner opined that the variable "X" would otherwise be indefinite because filters which capture at 90% a particle diameter of, for example 1μm, would also capture a particle diameter of greater than 1μm.

However, as explained during the interview, "X" is not a physical limitation of the filter but rather is a conventional standard used to identify the internal, microscopic structure of a filter. Accordingly, it is respectfully submitted that the Examiner's assertion is not relevant to claim definiteness because the conventional standard would be recognized by one of ordinary skill in the art, in which the "X" value merely represents the particular grade of the filter using common terminology. The Examiner appears to believe that the wording of the description for "X" will change the scope of the claimed invention. However, whether "X" is described as "a particle diameter" or a "a smallest particle diameter" does not affect claim scope but merely changes the title/name of the filter away from conventional grade terminology.

As noted above, "X" is merely a title/name which identifies a particular grade of a filter which has been standardized in the industry. One of ordinary skill in the art will recognize that X=2μm and X=.2μm, *by definition*, refer to different filters. In this regard, the Examiner's example on page 3, lines 3-8 of the outstanding Office Action purportedly evidencing why claim 1 is indefinite, is based on the false assumption that X=2μm and X=.2μm can refer to the same membrane. For the Examiner's reference, attached hereto are two technical publications (ROT FILTER published by Ameroid and an article entitled "Introduction of Membranes and Modules" published by Kuraray Co.; English translation included) which evidence that the 90% trapping ratio is defined in terms of a particle size rather than a smallest particle size when identifying a specific filter grade. For example, on page 2 of ROT FILTER there is a specification table which identifies different filter grades/models (e.g., ROT-7HCS, ROT-10HCS, etc.) based on the industry standard of removing 5μm particles over 90% (notwithstanding the possibility that particles greater than 5μm may also be removed). Similarly, on page 4 of the English translation of the tables in the Kuraray article, a table entitled

"Basic Performance of Kuraray Hollow-Fiber Membranes" lists various filter grades based on a 90% trapping ratio for a set particle diameter (e.g., SF-301(0.04μm), SF-401(0.10μm), etc.)(two published technical specifications of Kuraray filters indexed in terms of the 90% trapping ratio also enclosed for the Examiner's reference). As evidenced by the aforementioned publications, one of ordinary skill in the art would recognize that the recitation "where (X) is a particle diameter of particles captured when the particle trapping ratio is equal to or more than 90 % in the case where the filtration is done under an elevated pressure of 0.1 MPa" identifies a given filter grade based on industry standards. For example, 0.04μm would embody the SF-301 Kuraray brand. Whether 0.04μm is ***named*** as the smallest particle diameter filtered at 90% is completely irrelevant. Rather, in this example, the microscopic structure of the SF-301 brand membrane ***identified*** by 0.04μm is relevant. Again, the particle size at a 90% trap ratio is an industry classification where the particle diameter is merely a named identifier rather than a functional/operational characteristic of the filter. Accordingly, consistent with industry practice, there is no need to amend claim 1 to recite "where (X) is a smallest particle diameter of particles captured..." as that would stray away from the cataloging names currently used in the industry.

Based on all the foregoing, it is respectfully submitted that the claims are definite. Accordingly, it is respectfully requested that this rejection be withdrawn.

Claims 1, 3, 6-8 and 10 stand rejected under 35 U.S.C. § 112, second paragraph. It is respectfully submitted that the enclosed amendment obviates the alleged indefiniteness. Accordingly, it is respectfully requested that this rejection be withdrawn.

Claims 1, 3, 6-8 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over JP '095 in view of JP '758 or JP '406. Claims 1 and 6 are independent. This rejection is respectfully traversed for the following reasons.

A. Claim 1

Claim 1 recites in pertinent part, "the mean maximum length of pores in the filtration layer is designed such that (X) and (Y) fall within the range defined by plotting the following 10 points on the XY plane, where (X) is a particle diameter of particles captured when the particle trapping ratio is equal to or more than 90 % in the case where the filtration is done under an elevated pressure of 0.1 MPa, and (Y) is a value designated as RFL obtained by dividing (L) by (X), that is, (Y = L/X): (X, Y) = (0.055, 2) (1, 1.5) (2, 1) (5, 0.5) (10, 0.3) (10, 4) (5, 6) (2, 10) (1, 15) (0.055, 25)." The Examiner relies exclusively on JP '095 as alleged disclosing this feature of the present invention. However, it is respectfully submitted that JP '095 is completely silent as to a filter configuration satisfying the recited parameters.

During the interview, the Examiner stated his belief that the prior art device would inherently include a filter within the claimed range for "X" and the RFL value "Y." However, "inherency may not be established by probabilities or possibilities," *Scaltech Inc. v. Retec/Tetra*, 178 F.3d 1378 (Fed. Cir. 1999). In this case, the Examiner at best can assert only that the prior art may possibly contain a filter within the claimed range which is not sufficient to establish inherency. In any event, it is respectfully submitted that JP '095 does not disclose or suggest, or enable, a filter within the claimed range for "X" and the RFL value "Y." To this end, it is noted that the sole inventor of JP '095 is Tooru Morita who is also an inventor of the present invention. The Examiner is directed to the attached Declaration by Tooru Morita, evidencing the salient distinction between the filters disclosed in JP '095 and those within the claimed range.

In sum, it is respectfully submitted that only the present application provides the needed know-how to effect a filter within the claimed range. Indeed, one of the features of the present invention is directed to the recognition of the correlation between "X" and "RFL" where the parameter "RFL" was conceived exclusively by Mr. Tooru Morita for the present application.

Moreover, it is respectfully submitted that this difference between the present invention and cited prior art can not simply be discounted via the theory of routine experimentation. The "routine experimentation" basis for an obviousness rejection can only be relied upon by the Examiner if the prior art first recognizes the modified parameter as a result-effective variable. In the instant case, only Applicants have recognized and considered the importance of the correlation between "X" and "RFL" as a result-effective variable, so that the Examiner can not rely on the obviousness-theory of "routine experimentation" as a basis for asserting obviousness thereof.

Indeed, as a result of intensive research, "the present inventor has found that the clogging of pores in a porous material is caused by solid particles, mostly depending on the maximum cross-dimensions of numerous pores existing surrounded with the fibrous frameworks in the filtration surface, which is the outermost surface portion of the filtration layer. Also, it was found that the flow rate in a steady state after some elapse of time as well as the flow rate in an initial stage was important to achieve satisfactory filtration property for a long period of time" (page 12, lines 15+ of Applicants' specification). Accordingly, only Applicant has recognized and considered these particular drawbacks (and their causes) of conventional filter configurations, and conceived of a novel filter construction which can make it possible to obviate said drawbacks.

The Examiner is directed to MPEP § 2144.05(II)(B) under the heading "Only Result-Effective Variables Can Be Optimized", which sets forth the applicable standard for determining result-effective variables:

> A particular parameter must first ***be recognized*** as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. (citing *In re Antonie*, 195 USPQ 6 (CCPA 1977)).

In the instant case, the cited prior art is completely silent as to correlation between "X" and "RFL" achieving a recognized result (indeed, the Examiner does not reference any portion of the cited prior art for this purpose); so that there is no basis for alleging obviousness thereof based on routine experimentation.

B. Claim 6

With respect to claim 6, the Examiner alleges that "[a]ffording unevenness … is inherent [in JP '095] since the surface would be uneven due to porosity and also due to the stretching." In order to further clarify the distinction between the present invention and JP '095, claim 6 has been amended to recite in pertinent part, "affording an unevenness ***of 20-200 μm*** to the outer surface of a porous expanded polytetrafluorethylene tube by ***flame treatment, laser irradiation, or plasma irradiation***." JP '095 fails to disclose or suggest the recited unevenness (i.e., 20-200μm) let alone the particular process used to effect the unevenness. Indeed, JP '095 is silent as to applying flame treatment, laser irradiation, or plasma irradiation treatment to the outer surface of the alleged tube, so that any alleged inherent unevenness would be well below the claimed range.

In this regard, only Applicants have recognized and considered the effects of providing unevenness to the tube and conceived of the novel processing to effect said unevenness. As described on page 20, lines 11+ of Applicants' specification, the afforded unevenness can make it possible to prevent the displacement of a porous expanded polytetrafluoroethylene tube and porous expanded resin sheet, as well as to prevent the sheet from floating and enhance their adherence by providing a load onto the sheet during or after lapping thereof. The cited prior art is silent as to such effects and provides no motivation for affording unevenness in the manner recited in claim 6.

The Examiner is directed to MPEP § 2143.03 under the section entitled "All Claim Limitations Must Be Taught or Suggested", which sets forth the applicable standard for establishing obviousness under § 103:

> To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)).

In the instant case, the pending rejection does not "establish *prima facie* obviousness of [the] claimed invention" as recited in the independent claims because the proposed combination fails the "all the claim limitations" standard required under § 103.

Under Federal Circuit guidelines, a dependent claim is nonobvious if the independent claim upon which it depends is allowable because all the limitations of the independent claim are contained in the dependent claims, *Hartness International Inc. v. Simplimatic Engineering Co.*, 819 F.2d at 1100, 1108 (Fed. Cir. 1987). Accordingly, as the independent claims are patentable for the reasons set forth above, it is respectfully submitted that all claims dependent thereon are also patentable. In addition, it is respectfully submitted that the dependent claims are patentable based on their own merits by adding novel and non-obvious features to the combination.

Based on the foregoing, it is respectfully submitted that all pending claims are patentable over the cited prior art. Accordingly, it is respectfully requested that the rejection under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

Having fully responded to all matters raised in the Office Action, Applicants submit that all claims are in condition for allowance, an indication for which is respectfully solicited. If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicants' attorney at the telephone number shown below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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